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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,947	10/05/1999	SUDHIR AGRAWAL	HYZ-050CP2	1312

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/412,947	AGRAWAL, SUDHIR	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 23-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 23-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11-19-2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. The rejection of claims 1-20 and 23-57 under 35 U.S.C. 112, first paragraph, as set forth in the Office Action mailed 5-18-2004 has been withdrawn in response to Applicant's arguments filed 10-15-2004. However, new grounds for rejection of claims 1-20, and 23-57, are set forth below.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 12-20, 39-43, 50, 53, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,624,293 in view of Cho-Chung, (US Patent No. 5,271,941), Prewett et al. (1996), and DasGupta et al. (US Patent No. 5,658,947).

The claims of the instant application and those of the copending application are both drawn to compositions comprising synthetic, modified oligonucleotides complementary to

nucleic acid encoding protein kinase A subunit RIα, wherein said oligonucleotides are hybrid, inverted hybrid, or inverted chimeric oligonucleotides. The claims of the instant application differ from the claims of the copending application to the extent that the instant claims read on compositions further comprising a second therapeutic agent that comprises an active ingredient for cancer therapy, particularly wherein the second therapeutic agent is an antibody that binds EGFR or a cytotoxic agent selected from the group consisting of taxanes, platinum-derived agents, and topoisomerase II-selective drugs.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention, to modify the compositions of the copending application to comprise a second therapeutic agent that is an active ingredient for cancer therapy in the design of the invention set forth in the instant claims. One of ordinary skill in the art would have been motivated to make this modification since antisense targeting PKA RIα *(see US Patent No. 5,271,941; it is noted that the prior art does not teach the hybrid, inverted hybrid or inverted chimeric structures of the instant invention),* and the second therapeutic agents recited in the instant claims (See for example Prewett et al. (1996), and DasGupta et al. US Patent No. 5,658,947) are described in the prior art as being useful for inhibiting the proliferation of cancer cells. It would have been obvious to combine two agents that are known to be useful for inhibiting the proliferation of cancer cells with the expectation that a combination would be formed, wherein said combination would be expected to have the same properties as the individual agents, namely for use in the inhibition of the proliferation of cancer cells. See MPEP § 2144.06 which states: "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same

purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

5. Claims 1-20 and 23-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/641,521. in view of Cho-Chung, (US Patent No. 5,271,941), Prewett et al. (1996), and DasGupta et al. (US Patent No. 5,658,947).

6. The claims of the instant application and those of the copending application are both drawn to methods of inhibiting the proliferation of cancer cells comprising the administration of synthetic, modified oligonucleotides that are complementary to nucleic acid encoding protein kinase A subunit RIα, wherein the modified oligonucleotide having from about 15 to about 30 nucleotides an being a hybrid, inverted hybrid, or inverted chimeric oligonucleotide. However the claims of the copending application differ from the instant claims because they do not recite the use of a second therapeutic agent that comprises an active ingredient for cancer therapy, particularly wherein the second therapeutic agent is an antibody that binds EGFR or a cytotoxic agent selected from the group consisting of taxanes, platinum-derived agents, and topoisomerase II-selective drugs.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the claims of the copending application to comprise the administration of a second therapeutic agent that is an active ingredient for cancer therapy in the design of the invention set forth in the instant claims. One of ordinary skill in the art would have been motivated to make this modification since antisense targeting PKA RIα *(see US Patent No.*

5,271,941; it is noted that the prior art does not teach the hybrid, inverted hybrid or inverted chimeric structures of the instant invention), and the second therapeutic agents recited in the instant claims (See for example Prewett et al. (1996), and DasGupta et al. US Patent No. 5,658,947) are all known in the art as being useful for inhibiting the proliferation of cancer cells. It would have been obvious to combine the two cancer cell inhibitory agents with the expectation that a composition would be formed that would have the same properties, namely for use in the inhibition of the proliferation of cancer cells. See MPEP § 2144.06 which states: "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

7. Claims 1-20 and 23-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of copending Application No. 10/854,989 in view Hausheer et al. (US 5,447,936).

8. The claims of the instant application and those of the copending application are both drawn to methods and compositions comprising synthetic, modified oligonucleotides and a second therapeutic agent. The claims of the instant application differ from those of the copending application to the extent that the second therapeutic agent encompasses an antibody that binds EGFR or a cytotoxic agent selected from the group consisting of taxanes, platinum-derived agents, and topoisomerase II-selective drugs, and the claims of the copending application encompass wherein the second therapeutic agent comprises a topoisomerase I inhibitor, and further wherein the inhibitor is CPT-11. It is first noted that instant claims 53 and 56 are

broadly drawn to any particular second therapeutic agent that is an active ingredient for cancer therapy, and copending claims are limited to wherein the second therapeutic agent comprises a topoisomerase I inhibitor. However, the claims of the copending application are an obvious variation of the instant claims since topoisomerase I inhibitors, in particular CPT-11, and therapeutic agents that encompass an antibody that binds EGFR or a cytotoxic agent selected from the group consisting of taxanes, platinum-derived agents, and topoisomerase II-selective drugs are all agents that are known in the art to be useful in cancer therapy. For example Hausheer et al. (US 5,447,936) describe the use of CPT-11 as a topoisomerase I inhibitor, and further describes this inhibitor as useful for inhibiting the growth of cancer cells (see col. 1-2).

It would have been obvious to one of ordinary skill in that art at the time of filing to modify the claims of the instant application to comprise the use of topoisomerase I inhibitors as a second therapeutic agent to be used as an active agent in cancer therapy. One of ordinary skill in the art would have been motivated to make this modification since the prior art clearly teaches that topoisomerase I inhibitors are useful for inhibiting the growth of cancer cells.

This is a provisional obviousness-type double patenting rejection.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1635

JLE